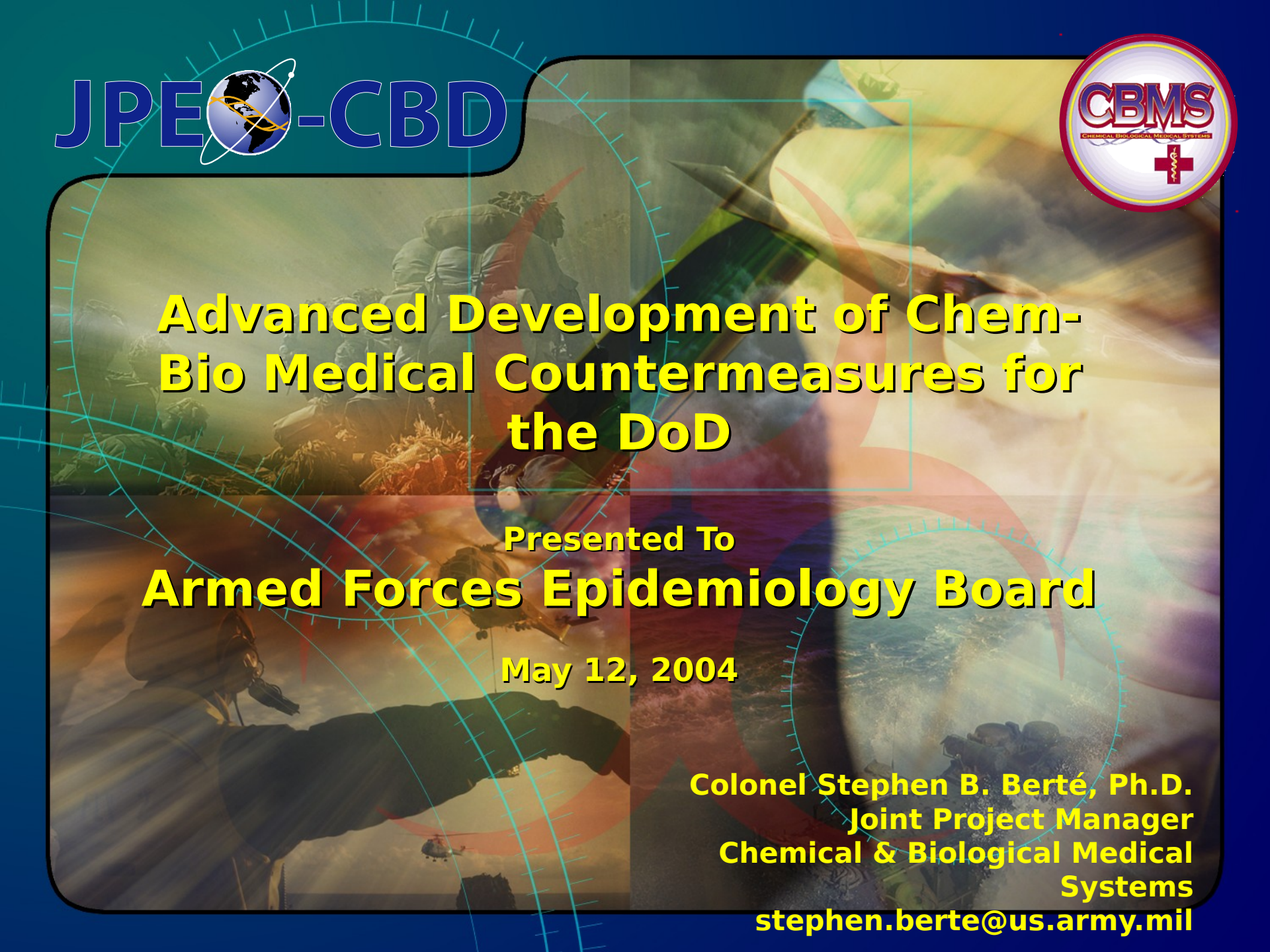


Advanced Development of Chem-Bio Medical Countermeasures for the DoD

Presented To

Armed Forces Epidemiology Board

May 12, 2004

Colonel Stephen B. Berté, Ph.D.
Joint Project Manager
Chemical & Biological Medical Systems
stephen.berte@us.army.mil

Agenda

- Organization
  - ChemBio Defense Program
  - Chemical Biological Medical Systems (CBMS)
- Challenges in DoD Medical CBD Acquisition
- Joint Vaccine Acquisition Program (JVAP)
- Medical Identification and Treatment Systems (MITS)
- Conclusion

Chem/Bio Defense Program Acquisition Organization

Defense Acquisition Executive (USD-ATL)

Army Acquisition Executive (ASA-ALT)

Joint Program Executive Officer

Joint Program Managers

Requirements

Joint Requirements Office J-8

Science & Technology

Defense Threat Reduction Agency - Chem/Bio Def Directorate

OSD Oversight

ATSD (NCB)

DATSD (CBD)

P.L. 103-160

Countering the Threat: System of Systems Approach

Sustained Combat Power

CB Threats & Hazards

Agent Delivery → Doses on Target → Downwind Dispersal → Doses Absorbed → Symptoms

Medical Pretreatment

Individual & Collective Protection

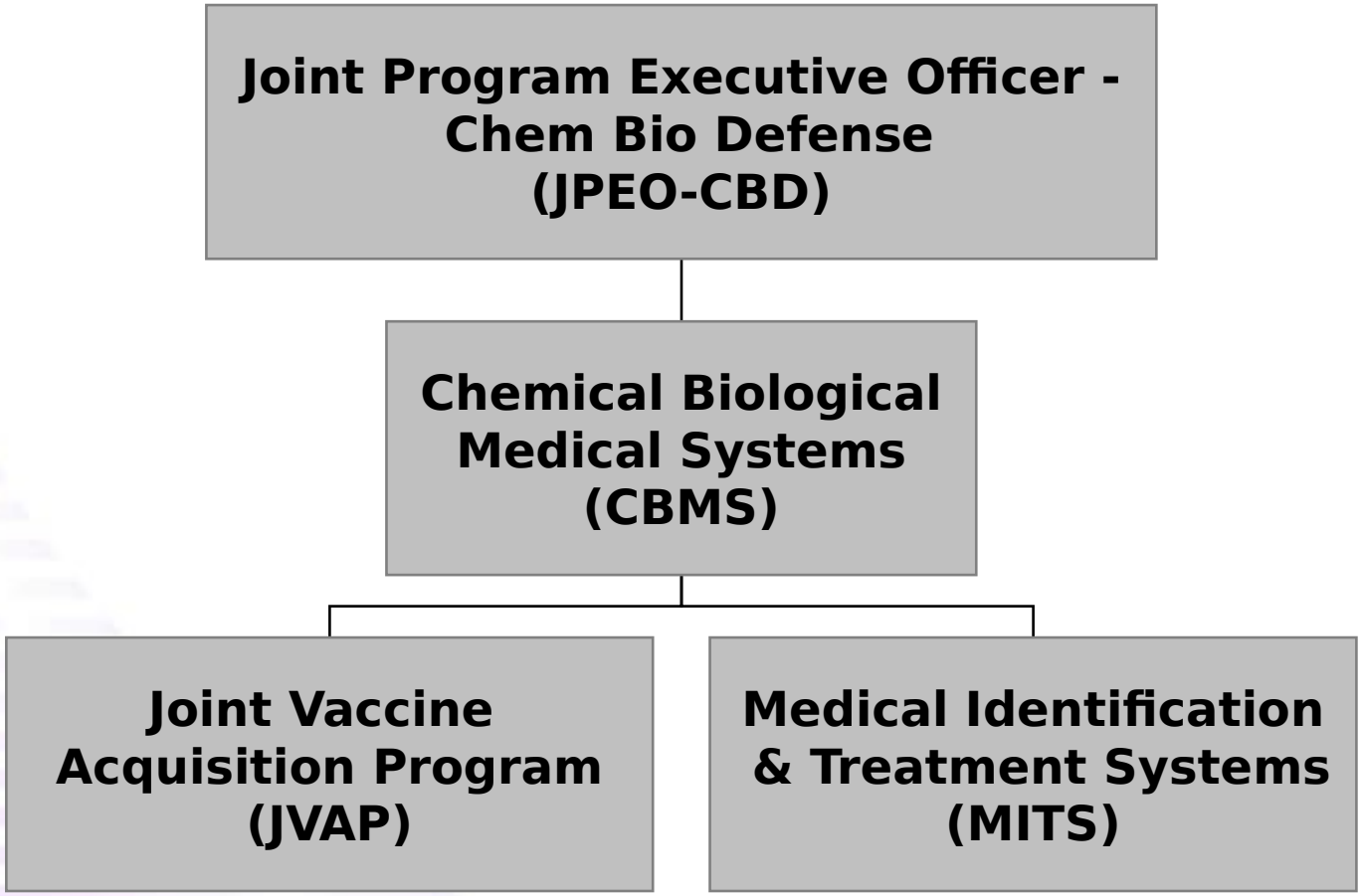
Medical Treatment

Contamination Avoidance & NBC Battle Management (Detection, Identification, Reconnaissance & Warning)

Installation Force Protection

Decontamination, Restoration

Chemical Biological Medical Systems (CBMS)



CBMS Mission

Develop, procure, field, and sustain premier *medical protection and treatment capabilities* against chemical and biological warfare agents.

Challenges in DoD Medical Product Development

- **FDA laws apply to all including DoD**

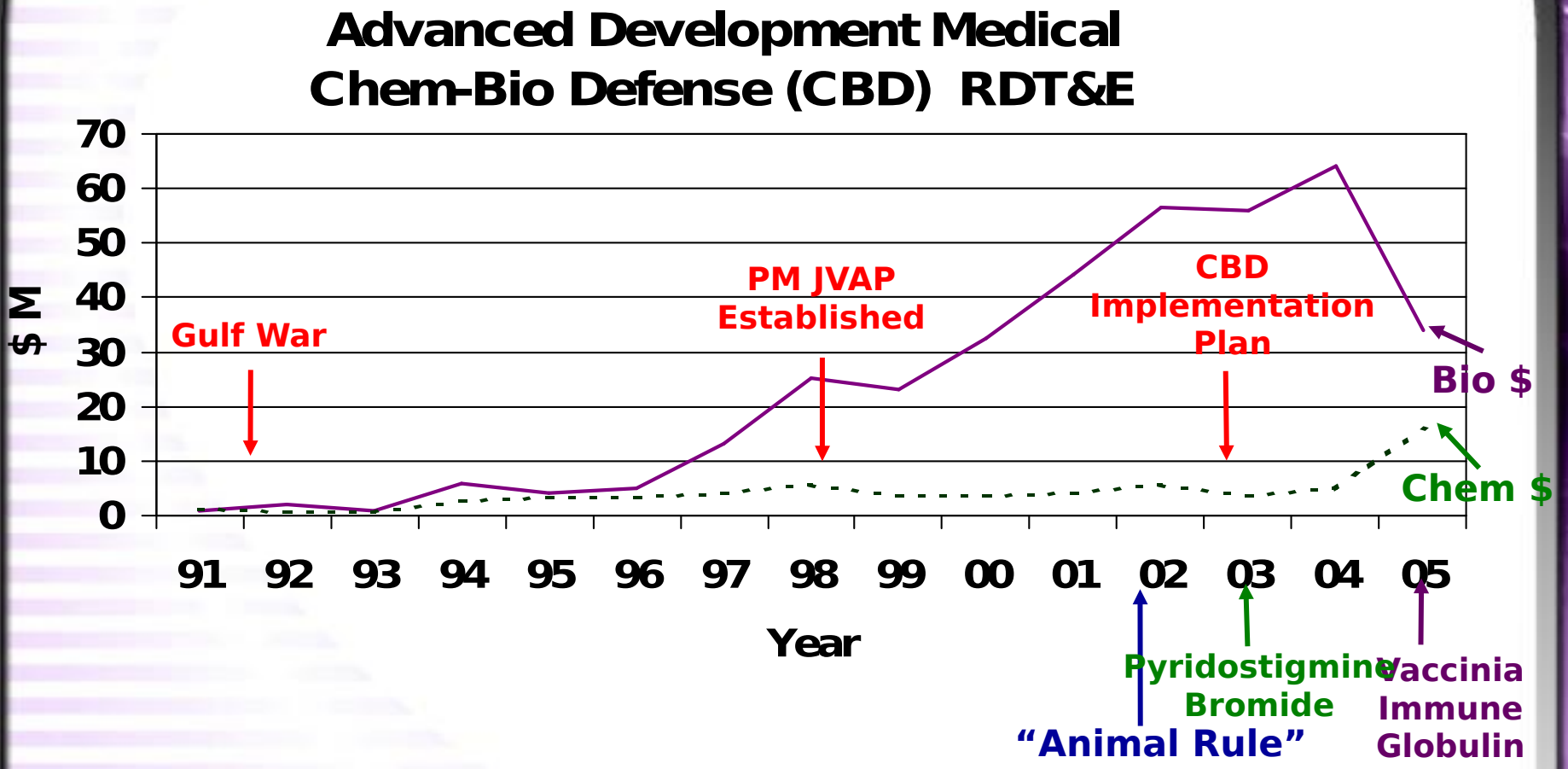
- **Meet prioritized warfighter needs within available resources**

- **Prove efficacy of Chem/Bio Defense medical products**

JVAP Mission

Aggressively develop, produce, and stockpile *FDA licensed vaccine systems* to protect the Warfighter from biological agents.

Medical Countermeasures Responding to Warfighter Needs



- Industry clinical trial development phase averages 6+ years
- Vaccine Prime Systems Contract (PSC) is 6 years old

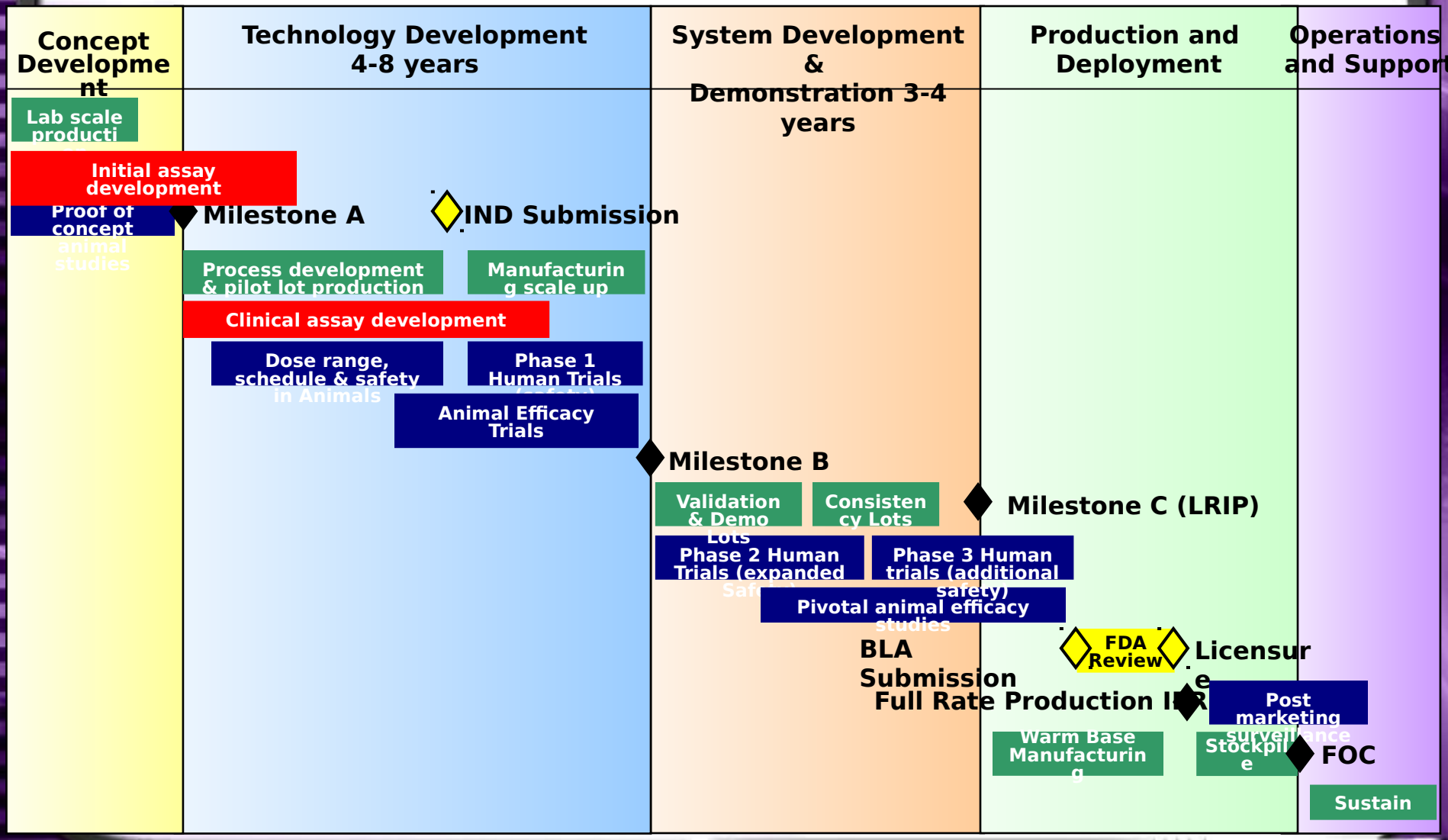
Medical Acquisition Strategy

- Addresses user requirements based on Chairman of the Joint Chiefs of Staff priorities
- Develops FDA licensed chemical and biological defense (CBD) medical products
- Leverages international partnerships, other government agencies, and industry
- Manages product line within available resources
  - Funds product development efforts to minimize schedules
  - Expands or contracts product line based on available funding

DoD and FDA Process Integration

- FDA process drives cost, schedule and performance
- DoD 5000 is tailorable; adjustments can and are made to accommodate the FDA process
- Medical corollaries exist for DoD 5000 TRLs
- Evolutionary Acquisition is used when possible within the FDA process
- Technology Insertion discouraged by FDA process
- Requirements must define product performance parameters early (MS A)

Integration of FDA Regulatory Process and DoD Acquisition Model for Vaccines



Industry Standard

- **Industry trend:**
  - **Clinical trial development times are increasing**
  - **4 yrs in early 1990's to 6+ years in early 2000's**
- **CBMS projected clinical trial development times are:**
  - **Botulism vaccine = 6 yrs (FDA Licensure: FY12)**
  - **Plague vaccine = 5 yrs (FDA Licensure: FY11)**
  - **Advanced Anticonvulsant System = 7 yrs (FDA Approval FY11)**
- **CBMS schedules are in line with industry standard**
- **CBMS continues to explore ways to shorten schedules**

Interagency Challenges

- **Emphasis:**
  - **DoD = prevention; DHHS = treatment**
- **Impact of BioShield funding to be determined**
- **Leveraging DHHS efforts that are:**
  - **focused on FDA *licensure***
  - **meet *warfighter requirements***
- **DoD-DHHS: No significant gaps; some overlap; some complementary programs**

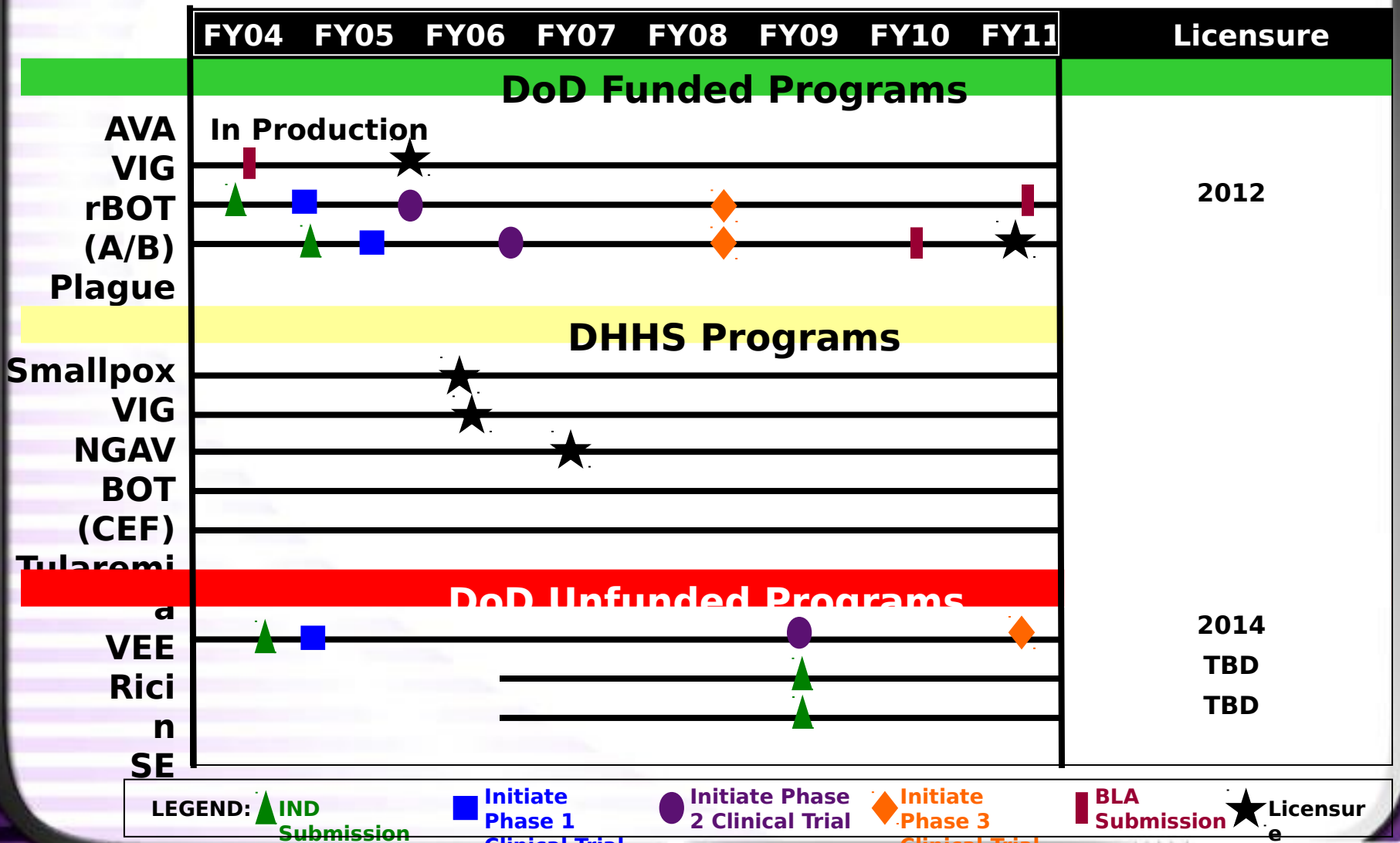
JPEO-CBD

Meeting Warfighter Needs

CBMS

Vaccine	*DoD*	*DHHS*	*Remarks*
Anthrax	X	X	AVA; DHHS developing follow-on
Botulinum Toxin	X	X	DHHS leveraging DoD program
Smallpox	X	X	DoD: VIG; DHHS: Vaccine & VIG
Plague	X	X	DoD is lead program
Ricin Toxin	X		Adv Dev ca. FY06
Encephalitis Virus	X	X	DoD: VEE; DHHS far from adv dev
Tularemia	X	X	DoD hand off to DHHS for FY04
Staph Enterotoxin	X		Adv Dev ca. FY06
Brucella	X		Adv Dev ca. FY07-08
Ebola / Marburg	X	X	Adv Dev ca. FY10

JVAP: Meeting Warfighter Needs



Medical Identification & Treatment Systems

Develop and acquire safe, effective, and *FDA-approved* products for *prophylaxis, treatment, and diagnosis of chemical and biological* warfare agent exposure.

Chemical Defense Medical Products

FDA Approved

- **M291** Skin Decontaminating Kit
- **RSDL** - Reactive Skin Decontamination Lotion
- **CANA** - Convulsant Antidote Nerve Agent
- **MANAA** - Medical Aerosolized Nerve Agent Antidote
- **Sodium Thiosulfate** for Cyanide Poisoning
- **SERPACWA** - Skin Exposure Reduction Paste Against Chemical Warfare Agents
- **ATNAA** - Antidote Treatment, Nerve Agent Autoinjector
- **SNAPP** - Soman Nerve Agent Pretreatment Pyridostigmine

Chemical Defense Medical Products

Upcoming Products

- **AAS – Advanced Anticonvulsant System : replaces CANA (diazepam) with midazolam – more effective for seizures**

  (MS B - FY04)

- **Next Generation Oxime: The Improved Nerve Agent Treatment System (INATS) using a new oxime will replace 2 PAM – more effective against Non-Traditional Agents (NTAs)**

  (MS A - FY04; MS B - FY06)

- **BioScavenger – Recombinant Butrylcholinesterase**

  (MS A - FY07)

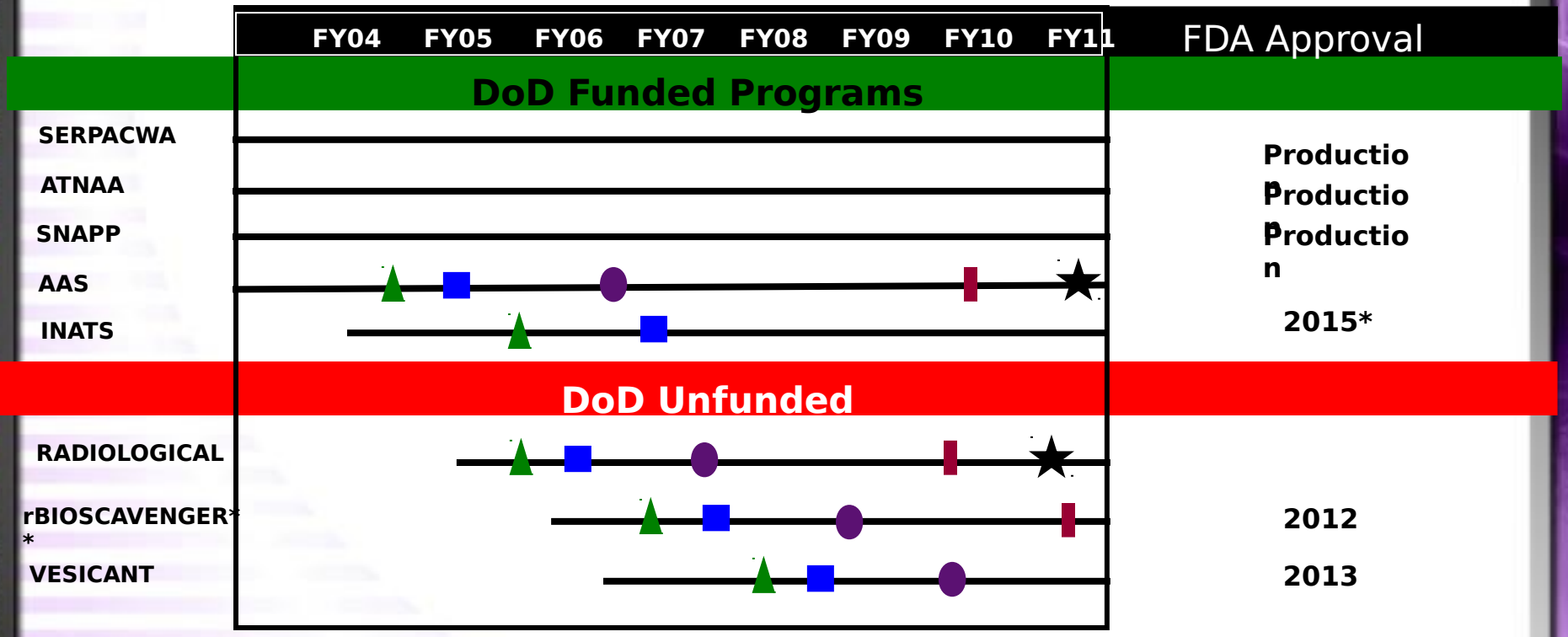
MITS Diagnostic System and Critical Reagent Programs

- **Joint Biological Agent Identification and Diagnostic System (JBAIDS)**
  - **Portable platform for BWA detection and diagnosis (FDA)**
- **Critical Reagents Program (CRP)**
  - **Provides quality antigen-antibody and PCR reagents to support different BWA detector platforms**

Joint Biological Agent Identification and Diagnostic System (JBAIDS)

- PCR medical diagnostic system:
  - Spiral Development: Detection to diagnostics
  - Environmental to clinical
- Government furnished agent targets and protocols
- ID in ≤ 60 minutes
- Portable and reusable
- Block upgrades:
  - Increase diagnostic capabilities
  - Reduce size and logistics tail
  - Tie into electronic medical reporting systems

MITS: Meeting Warfighter Needs

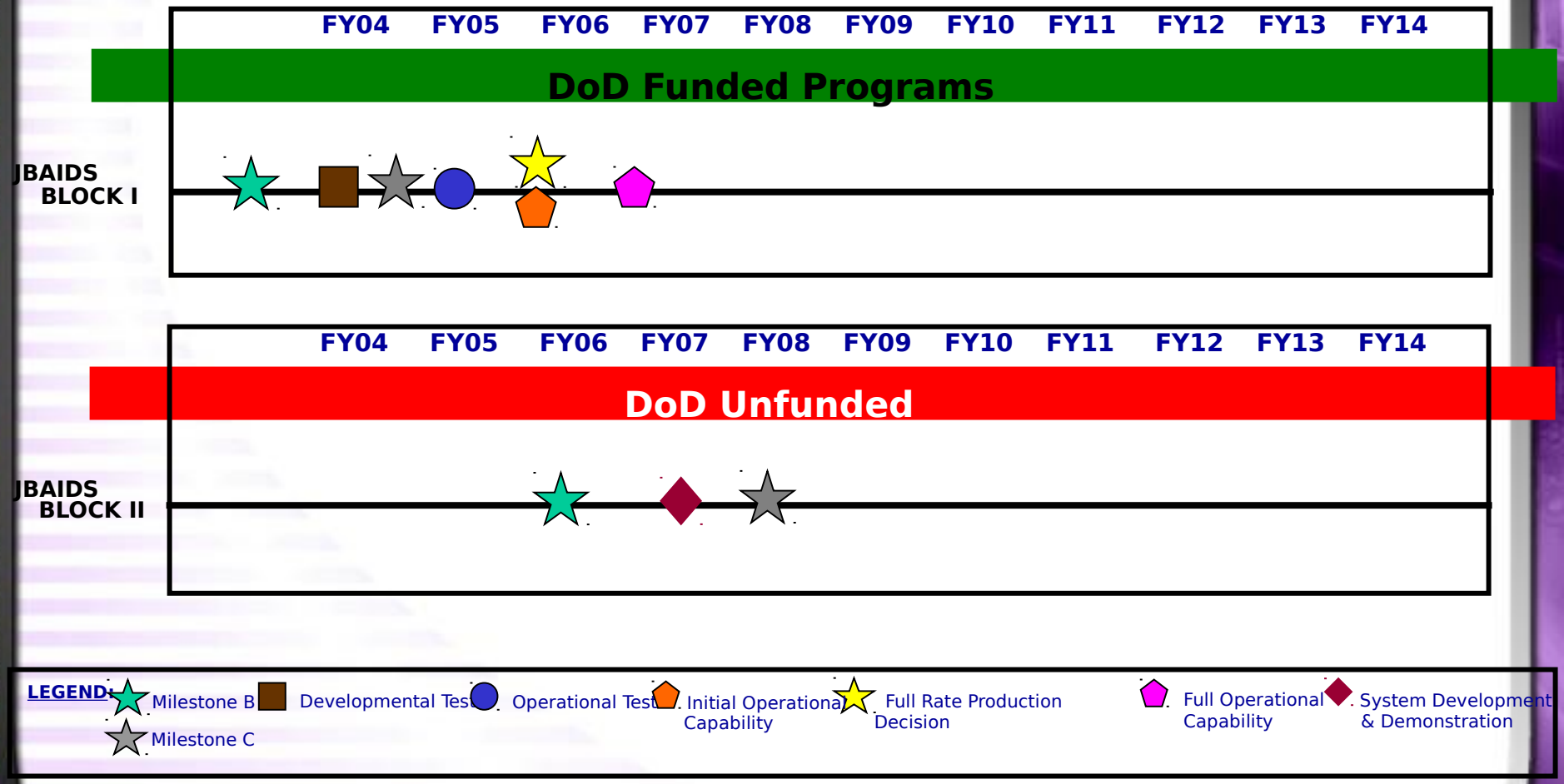


LEGEND: IND Submission | Initiate Phase 1 Clinical Trial | Initiate Phase 2 Clinical Trial | NDA Submission | FDA Approval

* UFR submitted that will accelerate FDA approval by four years

** Recombinant BioScavenger

MITS: Meeting Warfighter Needs



DoD Medical Chem-Bio Achievements

FY99

- Vaccinia Immune Globulin (VIG) Investigational New Drug (IND) application submitted to FDA

FY00

- Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) approved by FDA (U.S. Army Medical Research & Materiel Command product [USAMRMC])

FY02

- Smallpox vaccine IND submitted
- Bioport produces first Anthrax Vaccine Adsorbed (AVA) lot under new FDA license
- Smallpox Project Arrangement signed with Canada under CBR-MOU
- Antidote Treatment Nerve Agent Auto-injector (ATNAA) approved by FDA (USAMRMC product)

DoD Medical Chem-Bio Achievements

FY03 (continued)

- Next Generation Anthrax Vaccine (NGAV) IND submitted
- Pyridostigmine bromide tablets approved by FDA – first product approved in U.S. under FDA "animal rule" (USAMRMC & CBMS)
- Joint Service Personnel/Skin Decontamination System (JSPDS) approved by FDA (=RSDL)
- Joint Biological Agent Identification and Diagnostic System (JBAIDS): COTS fly off accelerates evolutionary program

FY04

- New contract signed with Bioport for AVA
- Interagency agreement with DHHS and DHS on AVA

DoD Medical Chem-Bio Projections

FY04

- **Submission of VEE vaccine IND**
- **Submission of Recombinant Botulism (AB) vaccine IND**

FY05

- **FDA licensure of VIG**
- **Submission of Plague vaccine IND**
- **JBAIDS Initial Operational Capability**

Take Aways

- CBMS program addressing DoD priority requirements
  - Focused on FDA licensure
  - Working within available resources
  - Leveraging Other Government Agencies and International partners
- CBMS acquisition strategy is in line with industry schedule standards for achieving medical product licensure
- DoD 5000 and FDA processes are integrated to achieve success

CHEMICAL BIOLOGICAL MEDICAL SYSTEMS

COL Stephen B. Berté

Joint Project Manager, CBMS

301-619-7400

stephen.berte@us.army.mil